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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/034,740 | 12/27/2001 | Bradley J. Enegren | PF00434 US | 1376 |
| 23608 | 7590 | 05/23/2005 | EXAMINER | |
| MEDTRONIC MINIMED INC. 18000 DEVONSHIRE STREET NORTHRIDGE, CA 91325-1219 | | | NASSER, ROBERT L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------|----------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/034,740 | ENEGREN ET AL. | |
| | Examiner | Art Unit | |
| | Robert L. Nasser | 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11 and 21-23 is/are rejected.
- 7) ☒ Claim(s) 3 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6-8, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Savage et al 5830209. Savage et al shows an implantable sensor system for taking readings from a patient including implantable sensors 52 and 54 at the distal tip of element 34, where the tip contacts bodily fluids, a flush sleeve 22 for directing flushing fluid to the tip (see column 7, lines 6-19) where the sensor and the flush sleeve are concentric. With respect to claim 2, there is a connector fitting 16 which helps support the sensors in the body. With respect to claim 4, the outer sleeve 2 and the sensor are in a "tight" fit arrangement. With respect to claim 6, the sleeve 22 is proximal to the sensor. With respect to claim 7, there is a protective sleeve 14. With respect to claim 8, it is inherent that there is a connector fitting for connecting the fiber 34 to the source/detector of the light. Claims 21 and 2 are rejected for the reasons given above.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage et al in view of Masterson et al 5891094. In figures 18 and 19 and the

accompanying discussion, Masterson et al further shows a one way valve in the flush line to prevent back wash of the flushing solution. Hence, it would have been obvious to modify Savage to use such a one way valve, to ensure proper flushing operation.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Savage et al in view of Newman et al 6358244. Newman et al et al teaches that saline is a known flush solution (see column 5, lines 47-65). Hence, it would have been obvious to modify Savage to use heparin, as it is merely the substitution of one known equivalent fluid for another.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Savage et al in view of Riccitelli et al 5166990. Riccitelli et al teaches that heparin is a known flush solution (see column 2, lines 39-64). Hence, it would have been obvious to modify Savage to use heparin, as it is merely the substitution of one known equivalent fluid for another.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Savage et al in view of Wulfman et al 2002/0007190. Wulfman further teaches the equivalence of wireless or wired connection between implanted temperature sensors and the monitor (see paragraph 145). Hence, it would have been obvious to modify Savage to use a wireless connection, as it is merely the substitution of one known equivalent transmission means for another.

Claims 3 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. These claims define over the art in that

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none of the art teaches the protector sleeve to prevent penetration of the sensor by the needle.

Applicant's arguments filed 3/14/2005 have been fully considered but they are deemed moot in view of the new grounds of rejection.

Applicant has asserted that the system of Savage is not "implantable" in that it is used for a procedure and removed from the body. The examiner disagrees for several reasons. First, when it is in use, the catheter of Savage is implanted. Second, the claim says implantable. The system of Savage is capable of being implanted and left in the body. Third, the record is devoid of a limiting definition of implantable. As such, the examiner is required to give the term its broadest reasonable interpretation. As such, a temporarily implanted catheter is implanted.

Applicant has further asserted that the sensors are not implantable. The examiner disagrees, noting that the sensors are capable of implantation.

Applicant has further asserted that the proximal end of the catheter is not "for" anchoring the system. The examiner notes that this is an intended use limitation and that the proximal end of the device of Savage is capable of anchoring the device within the patient.

Applicant has further asserted that the sensor tip of Savage is not for direct contact with fluids, since it measures tissue temperature. Ignoring the issue of whether there is body fluid in tissue, the limitation at issue is again an intended use limitation. Applicant must define structurally over the reference not functionally. The sensors of Savage are capable of contacting body fluid.

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Applicant has further asserted that the cooling fluid does not spray the tip In Savage. The examiner notes that cooling fluid is directed out of the catheter into a small blood vessel or small area. As such, it is inherent that some of the fluid will rebound of the boundaries of the area and pass by the tip.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

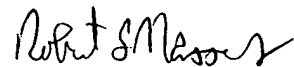
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736



RLN
May 17, 2005

ROBERT L. NASSER
PRIMARY EXAMINER

ROBERT L. NASSER
PRIMARY EXAMINER